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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,748	09/06/2005	Filippo Belardelli	0508-1115	4081

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,748	BELARDELLI ET AL.	
	Examiner	Art Unit	
	Laura M. Mitchell	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 October 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29 and 32-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-29, 32-36* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Claims 30-31 are cancelled.

Group I, claim(s) 1-10, 17-19, 26, 28-29, and 32-36, drawn to
a cell population of activated mononuclear antigen presenting cells (APCs),
a method for preparing mononuclear APCs comprising treating cells with ligands having receptors on the surface of blood monocytes,
a kit for preparing activated APCs comprising possibly a composition comprising a ligand having receptors on the surface of blood monocytes,
pharmaceutical composition or a vaccine comprising activated APCs and
a method for treating an infectious or neoplastic disease in a patient.

Group II, claim(s) 9, 11-15, 17-18, 20-24, 26-27 and 32, drawn to a method for preparing mononuclear APCs comprising treating cells with cytokines or inducers of interferon synthesis having receptors on the surface of blood monocytes,
a kit for preparing activated APC comprising possibly a composition comprising a Type I IFN or cytokine and compatible additives.

Group III, claim(s) 9, 16-18, 25-27 and 32-36, drawn to a method for preparing mononuclear APCs comprising treating cells with physical stress and a kit for preparing activated APC.

Group IV, claim(s) 9-24, 26-28 and 32-36, drawn to a method for preparing mononuclear APCs comprising treating cells with the combination of: ligands having receptors on the surface of blood monocytes, cytokines or inducers of interferon synthesis having receptors on the surface of blood monocytes and physical stress and a kit for preparing activated APC comprising possibly a composition with this combination.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature that links the inventions of Group I that defines an advance over the prior art is the cell population of APCs comprising the claimed limitations as well as a method of preparing the APCs comprising treating the cells with ligands having receptors on the surface of blood monocytes, and a method for using the APC population in a treatment method.

The special technical feature of Group II is a method for preparing APC cells comprising treating the cells with inducers of interferon synthesis or cytokines having receptors on the surface of blood monocytes; this defines an advance over Group I because it comprises the step of treating cells with a cytokine, which is not contemplated or disclosed in the methods of Group I. The special technical feature of Group III is a method for preparing the APC cells comprising treating the cells with physical stress; this defines an advance over Group I because it comprises the step of treating cells with physical stress, which is not contemplated or disclosed in the methods of Group I. The special technical feature of Group IV is a method for preparing APC cells comprising treating the cells with a combination of ligands having receptors on the surface of blood monocytes, with inducers of interferon synthesis or cytokines having receptors on the surface of blood monocytes and physical stress; this defines an advance over Group I because it comprises the step of treating cells with this combination which is not contemplated or disclosed in the methods of Group I.

In addition, the special technical feature of the method of Group II is distinct from Groups III-IV because Group II comprises the step of treating cells with a cytokine, which is not found in the methods of Group III-IV. The special technical feature of the

method of Group III is distinct from Groups II and IV, because Group III comprises the step of treating cells with physical stress, which is not found in the methods of Group II and IV. The special technical feature of the method of Group IV is distinct from Groups II-III because Group IV comprises the step of treating the cells with a combination of the stimuli detailed above, which is not found in the methods of Groups II-III. The cell population of Group I can be made by a process distinct from treatment of an APC cell with a ligand, such as by treating the cells with a cytokine (Group II), physical stress (Group III) or a combination of these stimuli (Group IV).

The claims of Group I have unity of invention because they are drawn to the following combination: A product, a process specially adapted for the manufacture of the said product, and a use of the said product; See 37 CFR 1.475.

The methods of Groups II-IV encompass additional processes of manufacture. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c). The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

1.) Ligands that are cell growth factors.

2.) Ligands that are complement polypeptides.

3.) Ligands that are muramyl dipeptide analogues.

4.) Ligands that are natural and synthetic detoxified endotoxin derivatives.

5.) A ligand that is histamine.

6.) A ligands that is vitamin D3.

7.) Ligands that are arachidonic acid metabolites.

8.) Ligands that are aminosulfonic acid derivatives.

9.) Ligands that are bacillus Calmette-Guerin or bacterial membrane extracts.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Ligands: claims 10, 18-19.

The following claim(s) are generic: 9, 17-18, 27 and 32.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or

corresponding special technical features for the following reasons: The ligand species are structurally, functionally and biochemically distinct molecules.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

1.) Cytokines that are IFN.
2.) Cytokines that are IL-12, IL-13, IL18.
3.) A cytokine that is GM-CSF.
4.) A cytokine that is TNFα.
5.) A cytokine that is TGFβ.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Cytokines and interferon: Claims 11-15, 20-24.

The following claim(s) are generic: 9, 17-18, 27 and 32.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: cytokine species are structurally, functionally and biochemically distinct molecules.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

1.) Physical stress that is separation of the cells from plasma.

2.) Physical stress that is an osmotic change.

3.) Physical stress that is an electrical field.

4.) Physical stress that is a temperature variation.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Physical stress: Claims 9, 16, and 25.

The following claim(s) are generic: 9, 17-18, 27 and 32.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The physical stresses for inducing formation of the IFN lack a special technical feature because each involves a distinct function. For example, the technical feature of one species comprises treating cells with an electrical field, which is functionally and structurally distinct from exposing cells to an osmotic change.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura M. Mitchell whose telephone number is (571) 272-8783. The examiner can normally be reached on M-F 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura M. Mitchell, PhD
Examiner
9/25/2007

CELINE QIAN, PH.D
PRIMARY EXAMINER